DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
Center for Veterinary Medicine

NOTICE OF CLAIMED INVESTIGATIONAL EXEMPTION

Form Approved: OMB No. 0910-0117
Expiration Date: 3/31/05

Submit this notice electronically to:
Food and Drug Administration
Center for Veterinary Medicine (HFV-)
7500 Standish Place
Rockville, Maryland 20855
(E-mail:cvmdcu@cvm.fda.gov)

DATE: **01/01/2001**
INAD / IFA NO: **I** **INAD** **0**
STUDY / TRIAL ID: **Study ID**
DRUG SHIPMENT NO: **Number of this shipment**
TYPE OF SHIPMENT: ☐ Initial ☐ Supplement ☐ Discontinued ☐ Other

Export Form Data

The sponsor, **COMPANY NAME**, submits a notice of claimed investigational exemption for the shipment or delivery of a new animal drug under the provisions of 21 CFR 511.1. This information is submitted in electronic form.

I. Shipment ☐ or Receipt ☐ Information

Add Password | Mail to | Reset

1. NAME(S) OF THE DRUG(S)
   Established name(s): **Established Name of Drugs (if multiple, please separate by commas)**
   Trade name(s): **Trade Name**
2. PROPOSED USE OF THE DRUG(S): **Indication(s)**
3. DATE OF DRUG SHIPMENT (OR RECEIPT): **01/01/2001**
4. TOTAL QUANTITY (WT. OR VOL.) AND CONCENTRATION OF DRUG(S) SHIPPED (OR RECEIVED): **Quantity of Drug**
5. TYPE OF STUDY / TRIAL: **Type of Study**
6. INTENDED USE OF STUDY OR TRIAL: ☐ Pivotal (intended for support of NADA or ANADA) ☐ Non-pivotal
7. NAME AND ADDRESS OF INVESTIGATOR:
   Investigator Name
   Investigator Address First Line
   Investigator Address Second Line
   Phone Number: **(000) 000-0000** **City** **State** **00000-0000**
8. LOCATION OF STUDY / TRIAL:
   Study Location Address First Line
   Study Location Address Second Line
   City **State** **00000-0000**
9. NAME AND ADDRESS OF STUDY MONITOR:
   Monitor Name
   Monitor Address First Line
   Monitor Address Second Line
   Phone Number: **(000) 000-0000** **City** **State** **00000-0000**
10. APPROXIMATE DATE OF STUDY / TRIAL Start: **01/01/2000** Finish: **01/01/2001**
11. PROTOCOL SUBMITTED TO CVM: ☐ Yes ☐ No
    If Yes, date submitted to CVM and/or CVM submission number: **01/01/2001** **E** **0**
12. SPECIES OF ANIMALS: **Animal** **Production Class**
13. SIZE AND TYPE OF ANIMALS: **Size and Type of Animals**
14. APPROXIMATE NUMBER OF ANIMALS (IN THIS TRIAL):
    Total: **0** Treated: **0** Control: **0**
15. NUMBER OF ANIMALS PREVIOUSLY USED:
    Total: **0** Treated: **0** Control: **0**
16. MAXIMUM DAILY DOSE: **Maximum Dose** AND DURATION: **Duration of Dosing**
17. METHOD OF ADMINISTRATION: **Route of Administration**
18. CONTRACT RESEARCH ORGANIZATIONS (CRO) USED: ☐ Yes ☐ No
    Name and address of CRO:
    CRO Name
    CRO Address First Line
    CRO Address Second Line
    Phone Number: **(000) 000-0000** **City** **State** **00000-0000**
    Description of obligations transferred to CRO: **Description of obligations**

Created by: Center for Veterinary Medicine
HFV-016 (301) 827-8277 EP

INAD/IFA No.: **0** DATE: **01/01/2001**

II. Animals Intended For Human Food Purposes

1. DATE OF CVM AUTHORIZATION LETTER: **01/01/2001**
2. WITHDRAWAL PERIOD: **Withdrawal Period**
3. ACKNOWLEDGEMENT: Acknowledgment that the date and place of slaughter will be reported to FDA and Dr. Janet Cornett, USDA/FSIS, Technical Service Center,1299 Farnam Street, Suite 300, Landmark Center, Omaha, NE, 68102, at least 10 days prior to shipment for slaughter. Experimentally treated animals will be identified to the inspector in charge of the slaughtering establishment when presented for antemortem inspection.

☐ Yes ☐ No

4. NOTIFICATION WAIVER: A waiver of requirements for notification of the date and place of slaughter after a 30-day holding and observation period following the required withdrawal period has been granted by FDA.

☐ Yes ☐ No

III. Investigational New Animal Drug Labeling (Please select one)

1. NEW ANIMAL DRUGS FOR TESTS *IN VITRO* AND IN LABORATORY RESEARCH ANIMALS:

☐ ***Caution.*** *Contains a new animal drug for investigational use only in laboratory research animals or for tests* ***in vitro****. Not for use in humans.*

2. NEW ANIMAL DRUGS FOR CLINICAL INVESTIGATION IN ANIMALS:

☐ ***Caution.*** *Contains a new animal drug for use only in investigational animals in clinical trials. Not for use in humans. Edible products of investigational animals are not to be used for food unless authorization has been granted by the U.S. Food and Drug Administration or by the U.S. Department of Agriculture.*

3. NEW ANIMAL DRUGS FOR EXPORT IN ANIMALS:

☐ ***Caution.*** *Contains a new animal drug for use only in investigational clinical trials. Not for use in humans. Edible products from animals used for investigation are not to be used for food in any manner contrary to the requirements of the country in which the clinical trials are to be conducted.*

If the drug is intended for food-producing animals, the label must also bear:

☐ *No official withdrawal time has been established for this product under the proposed investigational use.*

IV. Sponsor Information

1. SPONSOR'S NAME: **COMPANY NAME**
2. SPONSOR'S ADDRESS: **Applicant Address First Line**
   Applicant Address Second Line
   City **State** **00000-0000**
3. SPONSOR CONTACT'S NAME: **Contact Name**
4. SPONSOR CONTACT'S PHONE NUMBER: **(000) 000-0000**
5. SPONSOR CONTACT'S E-MAIL ADDRESS: **Email Address**

NOTE: IF THE INVESTIGATION IS DISCONTINUED, THE CENTER FOR VETERINARY MEDICINE SHOULD BE NOTIFIED, GIVING THE REASON AND DISPOSITION OF THE DRUG.

V. Comments

Please enter any relevant comments here

Are there additional comments? ☐ Yes ☐ No